

BY-LAW #3A
Under Section 40(2)¹ of The Medical Act
LABORATORY FACILITIES

Preamble

This by-law applies as follows:

1. Pursuant to *The Medical Act*, ss. 40(1)², to all laboratory facilities in Manitoba in which services are performed by members of the College.
2. Pursuant to ss. 40(6)³ of *The Medical Act* and by direction of the Minister of Health, to laboratory facilities falling within the jurisdiction of the government of Manitoba.
3. Pursuant to ss. 40(6) and by agreement with the federal government, to laboratory facilities in Manitoba falling within the jurisdiction of the government of Canada.

ARTICLE 1 - DEFINITIONS

1(1) General

In this By-law:

"certificate of accreditation" means a certificate issued to a laboratory facility by the College certifying that it has received accreditation.

"clinical scientist" means an individual who:

- a. has satisfactorily completed a program in one of the disciplines of laboratory medicine at a university acceptable to the committee,
- b. has been awarded a Doctorate degree in that discipline of laboratory medicine,
- c. has completed an appropriate post-doctoral training program in the clinical aspects related to the doctoral degree at an institution acceptable to the committee, and
- d. has passed the certification examination of the Canadian Society of Clinical Chemists or its equivalent in the discipline in which the individual trained.

¹ Subsection 40(2) states:

40(2) The council may make by-laws as to all matters pertaining to the establishment and operation of such diagnostic and treatment facilities to ensure that the procedures and standards of care set by the council for the protection of the public are carried out in all such diagnostic and treatment facilities.

² Subsection 40(1) states:

40(1) The council may appoint a committee to be known as the "program review committee" which may investigate and inspect on behalf of the council all diagnostic and treatment facilities in which services are performed by members in Manitoba other than those which are under the jurisdiction of provincial or municipal governments and those facilities that are approved hospitals under *The Manitoba Hospitals Act*.

³ Subsection 40(6) states:

40(6) The program review committee may enter into agreements with the federal, provincial or municipal governments to apply the provisions of subsections (1), (2) and (5) of this section to any facilities or any portion of a facility falling within the jurisdiction of that government and such agreements shall specify the procedures not inconsistent with any Act to be followed when the program review committee believes that the facility does not appear to meet the required standards.

"committee" means the committee of the College responsible for the administration of this By-law.

“direct or indirect financial interest” means any interest owned by a member, by individuals connected by blood relationship, marriage or adoption to a member, by any corporation, proprietorship, partnership, society, business, association, joint venture, group or syndicate in which a member or any individual connected by blood relationship, marriage or adoption to a member have any interest.

"Director" means a Member or a clinical scientist approved by the College as responsible for the operation of a facility.

"facility" means a laboratory facility.

"laboratory assistant" means a qualified radiology technologist who has completed a limited course in laboratory technology and who is employed in a position consistent with that training as approved by the College.

"laboratory physician" means a physician who has met the requirements set forth in Article 4 of this by-law for approval as a laboratory physician.

“laboratory technician” means a person who has satisfactorily completed a training program, acceptable to the College, designed for tests listed in the Manitoba Health Physicians Manual as short list procedures, and who is employed in a position consistent with that training as approved by the College.

"laboratory technologist" means a person qualified by and registered with the Canadian Society of Medical Laboratory Sciences.

“multi-discipline laboratory” means a medical laboratory that performs services in more than one of the disciplines of laboratory medicine.

“Royal College” means the Royal College of Physicians and Surgeons of Canada.

"short list laboratory" means a laboratory which limits its services to those tests listed in the Manitoba Health Physicians Manual as short list procedures.

"technical staff" includes laboratory technologists, laboratory assistants, laboratory technicians and other individuals employed in a facility.

1(2) In this by-law, words and phrases defined in *The Medical Act* have the same meaning as in *The Medical Act*

ARTICLE 2 - FACILITY ACCREDITATION

2(1) A facility must obtain a certificate of accreditation from the committee before it provides or offers to provide any laboratory services.

2(2) Applications for accreditation of a facility must:

- (a) be made to the College by the Director of the facility,
 - (b) be made on the forms prescribed by the College,
 - (c) identify the owners of the facility,
 - (d) report any direct or indirect financial interest that a physician or a medical corporation has in the ownership of the facility and provide full particulars of that interest, and
 - (e) be signed by the Director.
- 2(3) The facility shall promptly inform the College of any changes in the information provided pursuant to the requirement of Article 2(2).
- 2(4) The accreditation process will include:
- (a) satisfactory completion of a pre-survey questionnaire;
 - (b) an on-site survey by one or more health care professionals who have expertise in the appropriate area of practice and who are designated by the College;
 - (c) review of the facility's compliance with the College's standards.
- 2(5) Unless a delay is requested by the facility and agreed to by the College, the date for the on-site survey must be fixed within sixty days of the completed application, but the on-site survey itself need not be completed within that time.
- 2(6) Where the committee deems it appropriate to do so pending the completion of the review process, it may grant provisional accreditation.
- 2(7) Within sixty days of the on-site survey, the committee shall notify the Director of its decision.
- 2(8) The options available to the committee are:
- (a) decline the application,
 - (b) if the committee is satisfied that a facility has met all of the requirements of this By-law, grant accreditation for a specified period of up to five years, or
 - (c) if the committee has identified deficiencies, but is satisfied that it is in the public interest to permit the facility to operate while it corrects the deficiencies, grant conditional accreditation with a specific period of time within which the facility must correct the deficiencies.
- 2(9) When a conditional accreditation is granted:
- (a) a letter shall be issued indicating that accreditation is conditional and specifying the date on which conditional accreditation will expire if the identified deficiencies are not corrected,
 - (b) the committee may extend the deadline for correction of one or more of the deficiencies if, in its sole discretion, it deems it appropriate to do so;
 - (c) the Director must provide a written response to each deficiency, specifying corrective action taken,
 - (d) a follow-up survey may occur if the committee so directs, and

- (e) full accreditation will be granted when identified deficiencies have been corrected to the satisfaction of the committee.
- 2(10) Where a facility is no longer being used, the committee may revoke the facility's certificate of accreditation.
- 2(11) If during the currency of a certificate of accreditation, the committee is of the opinion that a facility fails to meet the requirements of this By-law or is unsafe, the committee shall provide notice to the facility and shall review the facility's accreditation. Where the committee is of the opinion that a facility does not meet the required standards, the committee may report the matter pursuant to ss. 40(3)⁴ of *The Medical Act*.
- 2(12) In order to renew a certificate of accreditation, the facility must re-apply for accreditation at least six (6) months prior to the date the certificate of accreditation is to expire. The re-accreditation process will follow the same procedure as required for initial accreditation.
- 2(13) Accreditation status will be automatically reviewed if:
- (a) the Director changes
 - (b) there are changes in key personnel and technical staff, or
 - (c) there is a change in the ownership of the facility.

ARTICLE 3 - ELIGIBLE PROCEDURES

- 3(1) Upon granting a certificate of accreditation, the committee shall attach as a schedule to the certificate, a list of procedures which have been approved for the facility.
- 3(2) The schedule of procedures may be amended from time to time upon the application of the facility and the approval of the committee.

ARTICLE 4 – LABORATORY PHYSICIAN

- 4(1) A physician who wishes to provide services at a facility as a laboratory physician must apply to the College in writing on the form approved by the College. Upon request, the applicant shall provide proof of qualifications.
- 4(2) No physician shall provide services in a facility as a laboratory physician until his/her application has been approved by the College.

⁴ Subsection 40(3) states:

40(3) Where the program review committee reports to the council that a diagnostic and treatment facility does not appear to meet the required standards, the council shall consider the report and the provisions of Parts IX and X of this Act apply with all necessary modifications.

- 4(3) To be eligible for approval as a laboratory physician, the applicant must have one of the following qualifications or must satisfactorily complete an assessment acceptable to the College:
- a. entry on the Specialist Register of the College in one or more of the following fields:
 - i. Anatomical Pathology
 - ii. General Pathology
 - iii. Haematological Pathology
 - iv. Medical Biochemistry
 - v. Medical Microbiology
 - vi. Neuropathology
 - vii. Transfusion Medicine
 - viii. Medical Genetics
 - b. diplomat of the American Board of Pathology, or declared Board eligible by the American Board of Pathology.
 - c. registration with the College as having a "Certificate of Special Competence" as offered by the Royal College in the following fields:
 - i. Clinical Immunology and Allergy
 - ii. Endocrinology and Metabolism
 - iii. Haematology
 - d. eligible for examination by the Royal College in one of the following specialities based upon satisfactory completion of training:
 - i. Anatomical Pathology
 - ii. General Pathology
 - iii. Haematological Pathology
 - iv. Medical Biochemistry
 - v. Medical Microbiology
 - vi. Neuropathology
 - vii. Transfusion Medicine
 - viii. Medical Genetics
 - e. previous approval by the College as a laboratory physician.
- 4(4) Once a physician receives approval under Article 4(1) of this by-law, if the committee is of the opinion that the physician does not meet the requirements of this By-law or is not practicing in a safe manner, the committee shall provide notice to the physician and shall review the physician's approval. Where the committee is of the opinion that a physician does not meet the required standards, the committee shall refer the matter to the Registrar.

ARTICLE 5 - TECHNICAL STAFF

- 5(1) A laboratory technician may perform:
- a. any of those procedures as listed on the Short List by the Manitoba Quality Assurance Program,
 - b. prepare media and do venipunctures while under the supervision of an approved physician/clinical scientist.
 - c. other procedures as approved by the committee on an individual basis, taking into consideration the training and qualifications of the individual and the setting in which the individual will be employed.

5(2) Where a facility is considering employing an individual other than a laboratory technologist, a laboratory assistant, or laboratory technician to perform laboratory procedures, the facility must apply to the College for approval. Where the committee deems it appropriate in the particular circumstances, it may approve such individuals to perform laboratory procedures in the facility.

ARTICLE 6 - FACILITY DIRECTOR

6(1) Subject to subsections (2), (3), and (4), a facility shall appoint as Director a laboratory physician or a clinical scientist qualified in the appropriate laboratory discipline. The Director must be approved by the College.

6(2) In a multi-discipline laboratory, the Director must be a laboratory physician, but a section of a multi-discipline laboratory may be under the direction of a clinical scientist.

6(3) Any physician on the Manitoba Medical Register may be named as a Director of a short list laboratory.

6(4) A single discipline laboratory or a section of a multi-discipline laboratory may appoint a clinical scientist as Director only if the clinical scientist agrees in writing:

- a. to accept the responsibilities of the Director as set forth in this By-law, and
- b. to submit to the jurisdiction of this By-law as though he/she were a physician.

6(5) The Director shall have the effective control of the facility, and shall supervise and be responsible for all technical and professional activities of the facility, and, without limiting the generality of the foregoing, shall:

- (a) have control of employment of technical staff and other personnel, subject to the right to delegate day-to-day employment processes to the charge technologist.
- (b) ensure that the facility employs only laboratory technologists, laboratory assistants, laboratory technicians, or other individuals approved by the College for that facility.
- (c) assess the credentials and qualifications of laboratory physicians working in the facility to ensure that they meet the criteria stipulated in this By-Law.
- (d) subject to subsection (7) at least annually, visit and inspect the facility.

- (e) participate directly in the operation of the facility, subject to the right to delegate a portion of the work to laboratory technologists, laboratory technicians or laboratory assistants in the facility.
- (f) be available for consultation with referring physicians.
- (g) be responsible for the development of appropriate and up-to-date policy and procedure manuals, including acceptable staff health policies;
- (h) establish guidelines regarding potential health hazards to patients and personnel of the facility.
- (i) ensure that complete and accurate patient records and documentation relating to the operation of the facility and procedures performed are kept.
- (j) have access to all records and documentation relating to the facility and its operation.
- (k) ensure that adequate quality assurance and improvement programs are in place.
- (l) at least quarterly, review the facility's quality control records.
- (m) at least annually, review the facility's quality assurance and improvement programs.
- (n) ensure that there is no financial arrangement or consideration between the facility and the referring physician.
- (o) direct and maintain an emergency level of service for the continuation of essential patient services in the event of withdrawal of services by laboratory physicians or technical staff.
- (p) ensure that the schedule of procedures which have been approved for the facility is maintained on file at the facility.
- (q) ensure that the facility confines itself to the schedule of procedures approved for that facility.
- (r) ensure that, regardless of the name of the facility, the name of the Director is clearly posted, either on the exterior of the facility or in the reception area of the facility.

6(6) The Director shall be responsible to the College to ensure:

- (a) that there is full and complete reporting to the College of all required information, including but not limited to, submitting the following to the College:
 - (i) at least annually, a Director's annual review form,
 - (ii) an annual report regarding quality assurance and improvement programs in the facility,
 - (iii) a copy of the Director's Agreement form,
 - (iv) its quality control program participation results and, where an error occurs, a Director's Response Form providing an explanation,

and

(b) that fees payable to the College are submitted as required.

6(7) Where the Committee considers it impractical to require an annual site visit and inspection by the Director of a facility, the Committee, upon the written application of the Director, may waive the requirement. No waiver shall be for a period of greater than one year.

ARTICLE 7- RECORDS

7(1) Physicians shall maintain clinical records that meet the expected standards of medical record-keeping.

7(2) Where appropriate, clinical records shall include documentation related to the informed consent of the patient for the procedure(s) performed in a facility.

ARTICLE 8 - AUDIT AND QUALITY CONTROL

8(1) Facilities must:

- (a) have appropriate quality assurance and improvement programs in place, and
- (b) participate in the quality control programs mandated by the College.

8(2) The review of standards is not dependent solely on quality assurance and improvement programs but may, at the discretion of the committee, take into consideration all aspects of the staffing, equipment and operation of the facility.

ARTICLE 9 - EQUIPMENT AND SUPPLIES

9(1) All procedures and standards of care set by the College for the protection of the public shall be carried out in the facility.

9(2) All equipment shall be safe and well maintained and comply with applicable federal, provincial, and municipal legislation.

9(3) Sterilization techniques and the storage of medical supplies shall be consistent with the current, recognized requirements of institutional infection control practices.

9(4) The facility shall comply with all guidelines the College may issue on the subject of infection control practices in an office setting.

9(5) Waste handling and disposal procedures shall comply with all current legislated and/or recommended institutional waste handling and disposal practices.

ARTICLE 10 - APPEAL

10(1) The facility or a physician may appeal any decision of the committee to the Executive Committee by filing a Notice of Appeal with the registrar within thirty (30) days of being informed of the decision.

ARTICLE 11 - SURVEYS AND AUDITS

11(1) Facilities shall be subject to on-site survey by health care professionals, designated by the committee to conduct surveys, at any time.

11(2) Should access to the facility for any survey be refused, the committee may take such action it deems necessary including, review of the facility's accreditation status and referral pursuant to ss. 40(3) of *The Medical Act*.

ARTICLE 12 - FEES

12(1) The facility shall pay all expenses, charges and fees including any licence fees imposed by the committee, in respect of the administration of this By-law.

ARTICLE 13 – TRANSITION

(a) Notwithstanding Article 2(12) hereof, for any facility that had accreditation as June 21, 2002, the following shall prevail:

- (i) re-accreditation may be granted by the committee for a period of no greater than 5 years from December 31, 2002 based upon:
 - A. satisfactory completion of a pre-survey questionnaire, and
 - B. review of the facility's compliance with the College's standards.

(ii) the committee must establish a date for an on-site survey of the facility, to occur no later than December 31, 2007.

(b) After December 31, 2007, the provisions of Article 2(12) shall apply.